REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

DISPOSITION OF CLAIMS

Claims 46, 51, 54-60 are pending in this application. Claims 48 and 53 have been cancelled. Claims 46 and 60 have been amended as set forth above to more closely conform to the specification. Support for the limitation "osmotic core within an internal compartment" recited in claims 46 and 60 occurs throughout the specification, for example, on page 10, line 23.

INTERVIEW SUMMARY

An interview with the Examiner was conducted on July 5, 2006. The pending claims and how they distinguish over the Chen et al. and Bartoo et al. patents were discussed. With respect to Chen et al., the general thrust of the arguments presented to the Examiner is that the invention recited in claim 46 has two membranes that remain during dispensing of the therapeutic agent whereas in Chen et al. the outer membrane is water soluble and dissolves immediately in the environment of use, leaving a dosage form having a single-layer membrane. With respect to Bartoo et al., the general thrust of the arguments presented to the Examiner is that the first membrane of the dosage form recited in claim 46 of the instant application is responsive to osmotic pressure whereas the inner membrane of the dosage form disclosed in Bartoo et al. is responsive to pH.

Applicant wishes to note herein that the first membrane of the dosage form of the claimed invention can include a semipermeable composition as a hydrophobic substance, as described, for example, on page 13, lines 27-29 of the specification. Further, usage of the terms "first membrane" and "second membrane" indicates that these membranes are different in composition or configuration.

REJECTIONS UNDER 35 U.S.C. §102

A. Claims 46, 48, 51, 53-58, and 60 were rejected under 35 U.S.C. §102 as being anticipated by Chen et al. Claims 48 and 53 have been cancelled. Accordingly, the rejection of

claims 48 and 53 is moot. Reconsideration of the rejection of claims 46, 51, 54-58, and 60 is respectfully requested.

Chen et al. disclose a dosage form comprising a compressed core including a medicament and a water soluble osmotic agent with conventional excipients and a water soluble polymeric binder. The compressed core is coated with an inner sustained release layer consisting essentially of a plasticizer and a water insoluble polymer, such as ethylcellulose. Chen et al. teach that the combination of plasticizer and water soluble polymer allows water to be imbibed into the core even in the absence of a preformed aperture. Chen et al. disclose that cellulosic polymers, such as hydroxymethyl cellulose, may be combined with the water insoluble polymer in the inner layer to modify the permeability of the inner layer. The inner sustained release layer is coated with an outer immediate release layer including a medicament dissolved in a water soluble binder.

Chen et al. disclose a dosage form wherein the outer layer is made of a water soluble polymer and medicament and dissolves immediately in the environment of use. Once the outer layer dissolves, only the inner layer would remain. In other words, the dosage form in Chen et al. becomes a single-layer membrane dosage form once it reaches the environment of use. With the inner layer directly exposed to the environment of use, the water soluble polymer will leach out of the inner layer and would be unavailable to modify the permeability of the inner layer. In contrast, claim 46 recites a second membrane positioned over an outside surface of a first membrane. The second membrane comprises a semipermeable composition and maintains its physical and chemical integrity as the dosage form dispenses a therapeutic agent. The second membrane does not dissolve in the environment of use, as in the case of the outer membrane of the Chen et al. dosage form. Therefore, the second membrane can prevent the hydrophilic substance in the first membrane from prematurely leaching into the environment of use and becoming unavailable to modify the permeability of the first membrane while the therapeutic agent is dispensed.

Applicant respectfully disagrees with the Examiner that the teachings of Chen et al. meet the limitations of the claims. In particular, from the foregoing arguments, Chen et al. do not disclose a dosage form having the limitation, "a second membrane comprising a semipermeable composition positioned over an outside surface of the said first membrane, the second membrane being distinct from the first membrane, wherein the second membrane maintains its physical and

chemical integrity as the dosage form dispenses the therapeutic agent formulation," as recited in claim 46. The outer layer disclosed in Chen et al. is water soluble, immediately dissolves in the environment of use, does not comprise a semipermeable composition, and does not satisfy the limitation of the second membrane recited in claim 46. Further, the inner layer of the dosage form disclosed in Chen et al. cannot double up as the first and second membranes recited in claim 46. For the second membrane to protect the first membrane in the environment of use as described above, the second membrane must necessarily be different from the first membrane.

In view of the above, Chen et al. do not anticipate claim 46. Claims 51 and 54-58, which depend from claim 46, are also not anticipated by Chen et al. Claim 60 recites a method of delivering the dosage form of claim 46 to a subject and is also not anticipated by Chen et al. Withdrawal of the rejection of claims 46, 51, 54-58, and 60 is respectfully requested.

B. Claims 46, 48, 51, and 53-60 were rejected under 35 U.S.C. §102(b) as being anticipated by Bartoo et al. Claims 48 and 53 have been cancelled. Accordingly, the rejection of claims 48 and 53 is moot. Reconsideration of the rejection of claims 46, 51, and 54-60 is respectfully requested.

Bartoo et al. disclose a dosage comprising (a) an internal compartment comprising a beneficial agent, (b) an inside wall surrounding the compartment, the inside wall comprising a polymeric formulation that is sensitive to changes in pH, and (c) an outer wall comprising a semipermeable polymer. The inside wall is described in detail in column 4, lines 6-46 of the patent. While the polymeric formulation of the inside wall of Bartoo et al. may include a hydrophobic substance and a hydrophilic substance, Bartoo et al. do not disclose or teach that the hydrophilic substance included in the inside wall has an aqueous solubility that is sensitive to osmotic pressure.

Example 1 of Bartoo et al. discloses a dosage form having an inside wall including hydroxypropylmethylcellulose phthalate, cellulose acetate, sorbitol, and polyethylene glycol. The attached Declaration under 37 C.F.R. §1.132 demonstrates that the hydrophilic substance hydroxypropylmethylcellulose phthalate in the inside wall of the dosage form of Bartoo et al. has an aqueous solubility that is sensitive to changes in pH but insensitive to changes in osmotic pressure. The attached Declaration under 37 C.F.R. §1.132 demonstrates that the hydrophilic substance polyethylene glycol in the inside wall of the dosage form of Bartoo et al. has an

aqueous solubility that is insensitive to changes in pH and insensitive to changes in osmotic pressure. For comparative analysis, the Declaration under 37 C.F.R. §1.132 demonstrates that hydroxypropylcellulose, which is given as an example of a hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure in the instant application, has an aqueous solubility that is sensitive to changes in osmotic pressure. The Declaration under 37 C.F.R. §1.132 clearly demonstrates that Bartoo et al. do not anticipate an inner membrane comprising a hydrophobic substance and a hydrophilic substance, wherein the hydrophilic substance exhibits an aqueous solubility that is responsive to osmotic pressure.

Because Bartoo et al. do not satisfy all the limitations of claim 46, Bartoo et al. do not anticipate claim 46. Bartoo et al. also do not anticipate claims 51 and 54-59, because of their dependence from claim 46. Claim 60 recites a method of delivering the dosage form of claim 46 to a subject and is also not anticipated by Bartoo et al. Withdrawal of the rejection of claims 46, 51, and 54-60 is respectfully requested.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated April 6, 2006, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC 2762C1).

Respectfully submitted,

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